

**REMARKS****A. Status of the Claims**

Claim 1 has been amended to recite at least one dye in an amount effective to simulate a known amount of analyte. Support for this amendment can be found, for example, on page 7, lines 12-13, and page 5, lines 16-17 of the specification. Claims 17 and 18 have been amended to recite a process for preparing a secondary standard. Support for this amendment can be found, for example, on page 5, lines 19-23 of the specification. Claim 32 has been added. Claim 32 is the same as claim 1, as amended, except for the transitional phrase "comprising". Claims 1-32 are pending and at issue.

**B. Rejection Under 35 U.S.C. § 102**

Claims 1-6, 8-23, and 27-31 stand rejected as anticipated by U.S. Patent No. 6,485,703 (Cote).

**(i) Claims 1-16, and 32**

Cote discloses hydrogel particles which undergo a measurable change in at least one electrochemical or optical property as a function of interaction with one or more substance(s) to be detected (Cote, column 5, line 65 to column 6, line 1). An analyte sensitive compound, e.g. a pH sensitive dye, may be attached to the hydrogel or comprised within the hydrogel (Cote, column 6, lines 9-10).

The present invention relates to a secondary standard. The secondary standard comprises a dye which simulates a known amount of analyte. Claim 1 has been amended to recite a standard comprising at least one dye in an amount effective to simulate a known amount of analyte. Cote does not teach or suggest a dye in an amount effective to *simulate* a known amount of analyte. Instead, the dyes in Cote are present in amounts effective to produce noticeable changes upon *interaction with* the analyte (See Cote, column 8, lines 32-34). Accordingly, Cote

does not teach or suggest at least one dye in an amount effective to simulate a known amount of analyte, as recited in claims 1-16.

In response to applicant's Response dated November 26, 2003, the Examiner asserts that it is "not seen that 'consisting essentially of' excludes anything from the composition of [Cote]". Applicants respectfully submit that the claims are distinguishable over Cote regardless of the transitional phrase. Claim 32 has been added which mimics claim 1, as amended, but includes "comprising" language.

Nevertheless, applicants note that the analyte sensitive compound in Cote produces an electrochemical or optical change upon contact with the substance being detected, whereas the calibrating standards of the present invention do not contain an analyte sensitive compound. If the present compositions contained an analyte sensitive compound, i.e., were they to undergo a change upon contact with the substance to be detected, they could no longer serve as calibrating standards. Because the presence of an analyte sensitive compound would affect the basic and novel characteristics of the present invention, it is outside the scope of claim 1.

## (ii) Claims 17-31

In the Response dated November 26, 2003, Applicants stated that Cote does not disclose or suggest a process for preparing a standard, or a process for preparing a container for calibrating an instrument, comprising gelling a mixture. In response, the Examiner argues Cote's process necessarily and inherently can be used as a standard.

Claims 17 and 18 have been amended to recite a secondary standard. Cote does not teach a process for preparing a secondary standard, nor would such a result be inherent from the steps disclosed therein. In Cote, an analyte sensitive compound produces an electrochemical or optical change upon contact with the analyte. Hence, Cote implicitly requires the presence of an analyte. In contrast, secondary standards simulate a known amount of analyte, but do not contain

an analyte (see present application, page 5, lines 15-23). Therefore, the product resulting from Cote's process cannot necessarily and inherently be used as a secondary standard.

**B. Rejection Under 35 U.S.C. § 103(a)**

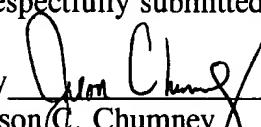
Claims 1-32 stand rejected as obvious over Cote in view of U.S. Patent No. 6,077,669 (Little).

Little discloses use of control samples containing known starting quantities of nucleic acid sequences (Little, col. 8, lines 8-12). Like Cote, Little also fails to disclose or suggest a standard comprising at least one dye in an amount effective to simulate a known amount of analyte, as recited in claims 1-16. Little similarly fails to disclose or suggest a process involving a secondary standard, as recited in claims 17-32, since Little's control samples contain the assayed entity (nucleic acids). Because each limitation is not taught or suggested, Applicants respectfully request that the obviousness rejection be withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

By   
Jason C. Chumney

Registration No.: 54,781  
DARBY & DARBY P.C.  
P.O. Box 5257  
New York, New York 10150-5257  
(212) 527-7700  
(212) 753-6237 (Fax)  
Attorneys/Agents For Applicant